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EXAMINER	
SALMON, KATHERINE D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/474,435	CAO ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,6-8,12-14,19-21,24-28 and 32-38* is/are pending in the application.

4a) Of the above claim(s) *24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,6-8,12-14,19-21,27,28 and 32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/14/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I Claims 2, 6-8, 12-14, 19-21, and 24-28, and 32-38 and the transformed cell species plant cell in the reply filed on 4/20/2007 is acknowledged.

The traversal is on the ground(s) that there has not shown that a search and examination of the entire application would cause a serious burden (p. 9 Reasons for Traversal).

This is not found persuasive because as set forth in the restriction requirement mailed 3/20/2007 there is a burden to search the distinct products of transformed cells, organism cells, or plants (p. 3 section 5 of Restriction Requirement). As stated in Section 5 of the Restriction Requirement each transformation involves a different step to transform the nucleic acid into the cells or plants and searching one transformed organism would not necessarily provide descriptive information on another transformed agenet.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/114151 filed 12/29/1998; 60/120644 filed 2/18/1999; 60/135825 filed 5/24/1999; 60/139932 filed 6/21/1999; 60/143994 filed 7/15/1999; 60/155422 filed 9/23/1999, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In the preliminary Amendment filed 4/30/2001 amended the instant specification to provide priority to the above application numbers. After a review of the prior applications, it does not appear that the instant claims have support in the above priority applications. The sequence identifiers in each case do not seem to correspond to the sequence identifiers in the instant case and therefore it does not seem that the prior filed applications have support for SEQ ID NO. 5272. For example, Application 60/114151 does not contain a SEQ ID No. 5272 and Application 60/135825 and 60/120644 both contain SEQ ID NO. 5272, but these sequences are not the same as the instantly claimed. In order to obtain priority of the prior filed applications, applicant is requested to disclose the specific sequence identifiers in each prior filed application which is identical to SEQ ID NO. 5272 of the instant application.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Specifically browser-executable code has been found on p. 9 lines 3-5; p. 36 lines 9 and 24; and p. 40 line 21.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 6-8, 12-14, 19-21, 27-28, and 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 6 are indefinite over the phrase "having the" in line 2 of Claim 2. It is unclear the "metes and bounds" of the claim because it is not clear if the substantially purified nucleic acid molecule can contain more nucleic acids than SEQ ID No. 5272. In other words it is unclear, by the language, if the substantially purified nucleic acid molecule "comprises", "consists", or have another degree of relationship with SEQ ID No. 5272 because the term "having the" is not defined. It is noted that in the following rejections, the phrase is being interpreted as "comprising".

Claims 2, 6-8, 12-14, 19-21, 27-28 and 32-38 are indefinite over the phrase "complement thereof". It is unclear the metes and bounds of this phrase because it is not known what is meant by "complements". Therefore "complements" can be

interpreted as the full complement of the entire sequence of SEQ ID No. 5272, or any percentage of complement, e.g. 10%, or 80% and any fragment size of SEQ ID NO. 5272. It is suggested that the claim be amended to e.g. "the complement" in order to overcome the indefiniteness of the phrase.

Claims 7 and 8 are indefinite over the phrase "having the" in line 2 of Claim 7. It is unclear the "metes and bounds" of the claim because it is not clear if the substantially purified nucleic acid molecule can contain more nucleic acids than SEQ ID No. 5272. In other words it is unclear, by the language, if the substantially purified nucleic acid molecule "comprises", "consists", or have another degree of relationship with SEQ ID No. 5272 because the term "having the" is not defined. It is noted that in the following rejections, the phrase is being interpreted as "comprising".

The term "sufficient" in claims 7 and 8 is a relative term, which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how much stability in the annealing should the first nucleic acid molecule to the second nucleic acid molecule to have sufficient stability.

Claims 12-14 are indefinite over the phrase "having the" in line 2 of Claim 12. It is unclear the "metes and bounds" of the claim because it is not clear if the substantially purified nucleic acid molecule can contain more nucleic acids than SEQ ID No. 5272. In other words it is unclear, by the language, if the substantially purified nucleic acid molecule "comprises", "consists", or have another degree of relationship with SEQ ID

No. 5272 because the term "having the" is not defined. It is noted that in the following rejections, the phrase is being interpreted as "comprising".

Claims 27-28, 32-38 are unclear because the phrase "between about" because the metes and bounds of the invention are not clear. As the CAFC noted, and affirmed, regarding the district court determination of this phrase in Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. (CA FC) 18 USPQ2d 1016 at page 1031 "the court held the "at least about" claims to be invalid for indefiniteness." The claims are indefinite with regard to the number of nucleotides because it is unclear if the claims are drawn to between 15 to 100 nucleotides or another range. The use of about before 15 and 100 makes the range smaller or larger than 15 to 100.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 28 recites the

broad recitation 18 to 50 bases, and the claim also recites 18 to 25 bases which is the narrower statement of the range/limitation. It is unclear if 18 to 50 bases need to be complementary or if 18 to 25 bases need to be complementary.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 6-8, 12-14, 19-21, 27-28, and 32-38 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to a substantially purified nucleic acid molecules having the sequence of SEQ ID No. 5272, substantially purified nucleic acid molecules comprising fragments of SEQ ID No. 5272 (as discussed in the 35 USC 112/second paragraph below the term "complementary" is interpreted as any fragment of SEQ ID No. 5272), and to substantially purified nucleic acid comprising a nucleic acid sequence having at least 90, 98, or 100% identity to SEQ ID NO. 5272. IN view of the "% identity" language, the claims further encompass mutants, allelic and splice variants of SEQ ID No. 5272 form non-Arabidopsis species.

The claimed nucleic acids are not supported by either a specific and substantial asserted utility or a well-established utility.

The specification discloses nucleic acid contig and singleton sequences consisting of SEQ ID Nos 1 to 81,306 were isolated from a library prepared from

Arabidopsis thaliana ecotype Landsberg erecta tissue (p. 3 liens 17-25 and Example 1). The present claims are limited to nucleic acid comprising SEQ ID NO. 5272 or fragments of SEQ ID NO. 5272 having 90, 98, or 100% identity with SEQ ID No. 5272. The specification does not state whether nucleic acid molecule of SEQ ID NO. 5272 constitutes a complete open reading frame and does not identify the location of the start and stop codons.

The specification also does not set forth a particular biological activity of SEQ ID No. 5272 nor does it describe any protein encoded by SEQ ID No. 5272. Therefore the specification has not established any specific function for SEQ ID No. 5272. Further, there has been no specific use for SEQ ID NO. 5272, The specification asserts the claimed nucleic acids can be used to determine transcriptional profiling to find, identify, and characterize counterpart gene in other species (p. 2 lines 10-15). However, such uses lack a specific and substantial utility. Such uses allow only for the identification and analysis of other nucleic acids. Because a utility has not been established for the present nucleic acid, the use of this nucleic acid to search for additional nucleic acids does not constitute a "real world" context of use.

The specification further contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for mapping studies, linkage analysis, constructing transgenic plants, and screening for traits or screening for polymorphisms (p. 2-3 and 17-18). However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes. Thereby, these uses are general and do not constitute a specific utility. While the use of the nucleic acid of SEQ ID No. 5272 in the disclosed

methods may eventually lead one to the identification of useful traits or specific polymorphisms or may eventually allow for the generation of transgenic plants, such uses constitute further research and experimentation and do not provide a readily-available, specific and substantial real-world use.

The specification also suggests that the proteins encoded by the claimed nucleic acids could be used to generate antibodies, which could be used for detection purposes (p. 16-17). Again, because a utility has not been established for the nucleic acid or the protein encoded thereby, use of the protein to generate antibodies to isolate and study proteins constitutes a research project and does not provide a specific and substantial utility.

The specification further contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for identifying markers and isolate promoters associated with proteins encoded by SEQ ID No. 5272 (15-16). The utility is not specific because it is a property of all plant nucleic acids that they could be used to search for and try to identify a polymorphism or promoter. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. As stated in Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), an invention does not have utility sufficient to satisfy §101 until it is "refined and developed" to the point of providing a specific benefit in currently available form. Id at 534-35, 148 USPQ at 695. In the instant application, Applicants have not set forth a single promoter or marker, which has been identified using the claimed SEQ ID NO: 5272.

All discussions regarding polymorphisms/markers in the specification are generic in nature. There is no showing of a reasonable expectation that the claimed nucleic acids could in fact be used to identify a specific promoter or marker. Even if a marker could be identified using the claimed SEQ ID NO: 5272, the specification has not disclosed a specific and substantial use for such an uncharacterized marker. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 5272 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of plant. Therefore, the nucleic acids of SEQ ID NO: 5272 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

The specification asserts that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in microarray as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific

utility. As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined.

The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 5272 or a protein encoded by SEQ ID NO: 5272 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of a mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid.

The use of the claimed nucleic acids to detect homologues in other plants and organisms such as alfalfa and barley (p. 21), is also not a substantial and specific utility. Since the functional activity of the presently claimed nucleic acids is unknown, and the functional activity of any putative homologues is unknown, the detection of such homologues does not provide an immediate benefit and serves only as a starting point for further research. In addition, the use of a nucleic acid in a microarray does not confer a patentable utility since all nucleic acids may be used in microarrays. Each of these asserted utilities are generic, rather than specific. Use of the claimed nucleic

acids in the above manners would not be meaningful in the absence of information regarding the specific biological activity or significance of these nucleic acids.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement as it applies to nucleic acids. See In re Fisher 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005). The Court held that 35 USC 101 requires a showing that a nucleic acid is both substantial and specific, stating that "not every 'use' that can be asserted will be sufficient to satisfy §101. " The court emphasized that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." Id. 76 USPQ2d at 1230.

The Fisher Court also held that none of the uses asserted by Applicants in that case were either substantial or specific because each of the "asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." The Court concluded that "granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility."

The instant situation is analogous to that which was addressed in Fisher. In the present case, Applicants have not established that the claimed nucleic acid encodes for a protein with a specific and substantial biological activity, or that the nucleic acid or protein could be used to identify a particular trait or to detect a particular polymorphism or promoter of known function. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 6-8, 12-14, 19-21, 27-28, and 32-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112/Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2, 6-8, 12-14, 19-21, 27-28, and 32-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is drawn to a substantially purified nucleic acid molecule comprising SEQ ID NO. 5272 or complement. Claim 6 defines the nucleic acid molecule as comprising one or more of a promoter region, regulatory region or intron region or parts of said regions. Claim 7 is drawn to a substantially purified first nucleic acid molecule, which is complementary to SEQ ID No. 5272 or complement. Claim 8 defines stringency conditions. Claim 12 is drawn to a substantially purified first nucleic acid homologous to SEQ ID NO. 5272 or complement wherein at least 90% of the nucleotide sequence is identical to SEQ ID NO. 5272 or complement. Claim 13 is drawn to a nucleic acid molecule 100% identical to a nonArabidopsis thaliana homologue. Claim 14 is drawn to a substantially purified nucleic acid molecule which is at least 98% identical to SEQ ID No. 5272 or complement. Claim 19 is drawn to a transformed cell comprising a homologous or complementary nucleic acid molecule comprising SEQ ID No. 5272 or

complement. Claims 20-21 define a transformed cell. Claims 27-28 and 32-38 is drawn to oligonucleotide nucleic acid molecules comprising between 15 0 100 nucleotides on a support.

The claims are drawn to substantially purified nucleic acids that are fragments of unknown size to SEQ ID No. 5272. The claims are drawn to any number of percent homology to SEQ ID No. 5272. Therefore the claims are drawn to a genus of nucleic acids of variants, homologues, and splice variants of SEQ ID No. 5272 without any defining characteristics of functional properties.

The claims define the nucleic acids in terms of their structure, but do not define the nucleic acids in terms of their functional properties. Accordingly, the claims are inclusive of nucleic acid molecules which have distinct biological activities from the nucleic acid of SEQ ID NO: 5272. The specification has not clearly set forth a biological activity for the nucleic acids of SEQ ID NO: 5272. Further, the specification does not set for a biological activity for putative mutant and allelic variants or splice variants or homologues of SEQ ID NO: 5272 which is encompassed by the broad claim language. Further, the specification does not describe the functional properties of the fragments of SEQ ID No. 5272 which is encompassed by the broad claim language.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID NO: 5272 will effect the functional properties of SEQ ID NO: 5272. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID

NO: 5272) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 5272 having unspecified functional activities different from that of SEQ ID NO: 5272.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

The specification fails to sufficiently describe the claimed invention in clear and exact terms so that a skilled artisan would recognize that the applicants were in possession of the claimed invention at the time of filing.

In analysis of the claims for compliance with written description requirement of 35

U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids and polymorphisms in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the genus of nucleic acids and polymorphisms encompassed by the broadly claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures,

diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

In conclusion, the limited information provided regarding SEQ ID No 5272 is not deemed sufficient to reasonably convey to one skilled in the art the description of all the fragments, mutants, homologues, and splice variants encompassed by the broad claim language.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2, 6-8, 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Accession Number AP000604 (NCBI website October 15, 1999).

The term "complement" is not defined in the instant specification; therefore the phrase may be read broadly. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *in re Morris* , 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *in re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification wherein the phrase "complement" can be read as any fragment which shares a percent identity with SEQ ID NO. 5272.

With regard to Claim 2, GenBank Accession Number AP000604 discloses a sequence which would be considered a complement of SEQ ID NO. 5272. The alignment presented below shows that GenBank Accession Number AP000604 shares a complementary sequence to SEQ ID NO. 5272 at particular segments of the sequence.

With regard to Claim 6, GenBank Accession Number AP000604 comprises the sequence of Chromosome 3, and therefore comprises nucleic acid sequence which are parts of promoter, regulatory, or intron regions.

With regard to Claims 7-8, GenBank Accession Number AP000604, discloses a substantially purified nucleic acid molecule of a complement of SEQ ID NO. 5272. Though GenBank Accession Number AP000604 does not teach hybridization

conditions, the Accession Number does teach the product claimed therefore would encompass the same functions as the claimed nucleic acid and would therefore hybridize with sufficient stability. MPEP §2111-14, first section, states "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." Therefore, for the purposes of examination, the functional limitations of hybridization set fourth in Claims 7-8 are considered not to have structural impact and will not be treated as limitations to the claims.

Claims 27-28 are being interpreted as comprising at least about 15 to about 100 nucleotides homologous or complementary to SEQ ID No. 5272, however, the claim is not limited in the size of the oligonucleotide nucleic acid molecule or the number of complementary nucleic acids. Because of the broad claim language of "comprising", the nucleic acid could comprise more than 100 nucleotides complementary. With regard to Claims 27-28, GenBank Accession Number AP000604 discloses a sequence wherein the nucleic acid comprises between about 15 to about 100 nucleotides homologous or complementary to SEQ ID No. 5272.

Alignment

Query represents SEQ ID NO. 5272 and Sbjct represents AP000604

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Query  2009   ATAGTTGGATTACGATTACTTTTGTCCTTCGGAATTACTTTTGATGTATTTTCTATTCTC  2068
              ||||||||||||||||||||||||||| ||||||||||||||||||||||||||||||||
Sbjct  57815  ATAGTTGGATTACGATTACTTTTGTCCTTAGGAATTACTTTTGATGTATTTTCTATTCTC  57874

Query  2069   TTTTGTTTTGTTTTGATGTTGATAATAACGAATTTTCCTTGAAATAAGAAAATCTGTTTC  2128
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||| |||||
Sbjct  57875  TTTTGTTTTGTTTTGATGTTGATAATAACGAATTTTCCTTGAAATAAGAAAATCAGTTTC  57934
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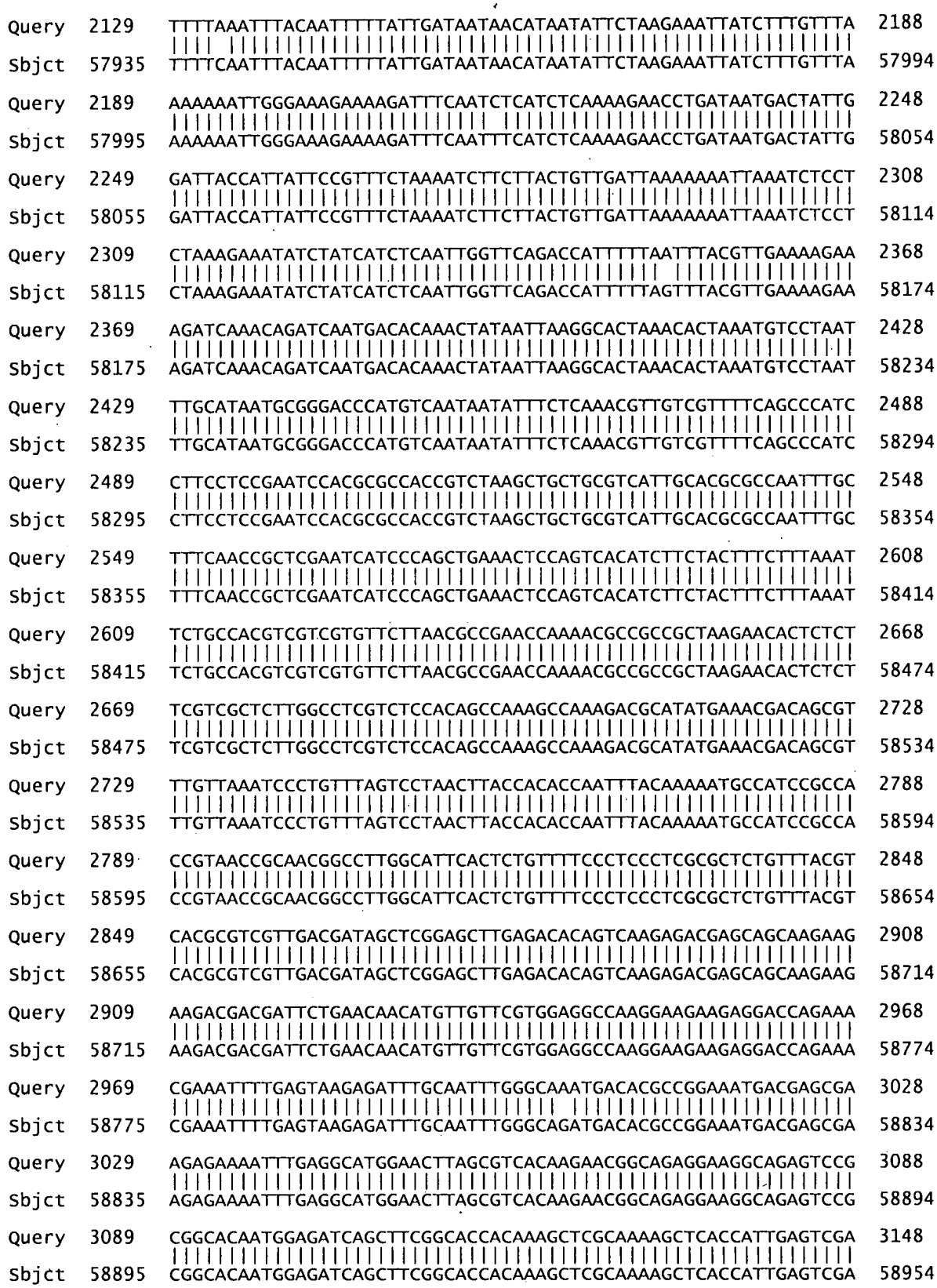
Query 2129 TTTTAAATTTACAATTTTTATTGATAATAACATAATATTCTAAGAAATTATCTTTGTTTA 2188
Sbjct 57935 TTTTCAATTTACAATTTTTATTGATAATAACATAATATTCTAAGAAATTATCTTTGTTTA 57994
Query 2189 AAAAAATTGGGAAAGAAAAGATTTCAATCTCATCTCAAAAGAACCTGATAATGACTATTG 2248
Sbjct 57995 AAAAAATTGGGAAAGAAAAGATTTCAATTTCATCTCAAAAGAACCTGATAATGACTATTG 58054
Query 2249 GATTACCATTATTCCGTTTCTAAAATCTTCTTACTGTTGATTAAAAAAATTAAATCTCCT 2308
Sbjct 58055 GATTACCATTATTCCGTTTCTAAAATCTTCTTACTGTTGATTAAAAAAATTAAATCTCCT 58114
Query 2309 CTAAAGAAATATCTATCATCTCAATTGGTTCAGACCATTTTTAATTTACGTTGAAAAGAA 2368
Sbjct 58115 CTAAAGAAATATCTATCATCTCAATTGGTTCAGACCATTTTTAGTTTACGTTGAAAAGAA 58174
Query 2369 AGATCAAACAGATCAATGACACAAACTATAATTAAGGCACTAAACACTAAATGTCCTAAT 2428
Sbjct 58175 AGATCAAACAGATCAATGACACAAACTATAATTAAGGCACTAAACACTAAATGTCCTAAT 58234
Query 2429 TTGCATAATGCGGGACCCATGTCAATAATATTTCTCAAACGTTGTCGTTTTCAGCCCATC 2488
Sbjct 58235 TTGCATAATGCGGGACCCATGTCAATAATATTTCTCAAACGTTGTCGTTTTCAGCCCATC 58294
Query 2489 CTTCCTCCGAATCCACGCGCCACCGTCTAAGCTGCTGCGTCATTGCACGCGCCAATTTGC 2548
Sbjct 58295 CTTCCTCCGAATCCACGCGCCACCGTCTAAGCTGCTGCGTCATTGCACGCGCCAATTTGC 58354
Query 2549 TTTCAACCGCTCGAATCATCCCAGCTGAAACTCCAGTCACATCTTCTACTTTCTTTAAAT 2608
Sbjct 58355 TTTCAACCGCTCGAATCATCCCAGCTGAAACTCCAGTCACATCTTCTACTTTCTTTAAAT 58414
Query 2609 TCTGCCACGTCGTCGTGTTCTTAACGCCGAACCAAAACGCCGCCGCTAAGAACACTCTCT 2668
Sbjct 58415 TCTGCCACGTCGTCGTGTTCTTAACGCCGAACCAAAACGCCGCCGCTAAGAACACTCTCT 58474
Query 2669 TCGTCGCTCTTGGCCTCGTCTCCACAGCCAAAGCCAAAGACGCATATGAAACGACAGCGT 2728
Sbjct 58475 TCGTCGCTCTTGGCCTCGTCTCCACAGCCAAAGCCAAAGACGCATATGAAACGACAGCGT 58534
Query 2729 TTGTTAAATCCCTGTTTAGTCCTAACTTACCACACCAATTTACAAAAATGCCATCCGCCA 2788
Sbjct 58535 TTGTTAAATCCCTGTTTAGTCCTAACTTACCACACCAATTTACAAAAATGCCATCCGCCA 58594
Query 2789 CCGTAACCGCAACGGCCTTGGCATTCACTCTGTTTTCCCTCCCTCGCGCTCTGTTTACGT 2848
Sbjct 58595 CCGTAACCGCAACGGCCTTGGCATTCACTCTGTTTTCCCTCCCTCGCGCTCTGTTTACGT 58654
Query 2849 CACGCGTCGTTGACGATAGCTCGGAGCTTGAGACACAGTCAAGAGACGAGCAGCAAGAAG 2908
Sbjct 58655 CACGCGTCGTTGACGATAGCTCGGAGCTTGAGACACAGTCAAGAGACGAGCAGCAAGAAG 58714
Query 2909 AAGACGACGATTCTGAACAACATGTTGTTCGTGGAGGCCAAGGAAGAAGAGGACCAGAAA 2968
Sbjct 58715 AAGACGACGATTCTGAACAACATGTTGTTCGTGGAGGCCAAGGAAGAAGAGGACCAGAAA 58774
Query 2969 CGAAATTTTGAGTAAGAGATTTGCAATTTGGGCAAATGACACGCCGGAAATGACGAGCGA 3028
Sbjct 58775 CGAAATTTTGAGTAAGAGATTTGCAATTTGGGCAGATGACACGCCGGAAATGACGAGCGA 58834
Query 3029 AGAGAAAATTTGAGGCATGGAACTTAGCGTCACAAGAACGGCAGAGGAAGGCAGAGTCCG 3088
Sbjct 58835 AGAGAAAATTTGAGGCATGGAACTTAGCGTCACAAGAACGGCAGAGGAAGGCAGAGTCCG 58894
Query 3089 CGGCACAATGGAGATCAGCTTCGGCACCACAAAGCTCGCAAAAGCTCACCATTGAGTCGA 3148
Sbjct 58895 CGGCACAATGGAGATCAGCTTCGGCACCACAAAGCTCGCAAAAGCTCACCATTGAGTCGA 58954

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Query  3149   TCTCTCTGGATCACCAGAAAGAAGTGAGAGAGAATTGGTTTGGAATGATGATGGTGGGAA  3208
              ||||||| ||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  58955  TCTCTCT-GATCACCAGAAAGAAGTGAGAGAGAATTGGTTTGGAATGATGATGGTGGGAA  59013

Query  3209   GAGAGATTTAAGGAAGAGATGTAAATGATTGAGGGAGAGAAAGAGCGGTGGAGTTTTTAT  3268
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  59014  GAGAGATTTAAGGAAGAGATGTAAATGATTGAGGGAGAGAAAGAGCGGTGGAGTTTTTAT  59073

Query  3269   GGTTCATGGTTGATGAGAGTAGTCTCTTCCACAGTTCACACATCAAAGAAACTTACATGA  3328
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  59074  GGTTCATGGTTGATGAGAGTAGTCTCTTCCACAGTTCACACATCAAAGAAACTTACATGA  59133

Query  3329   GCCATAATTTTTTAGGGAAATGAAATGAATGGTGTTTGTAGAATTGGAGAGAATGACGTG  3388
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  59134  GCCATAATTTTTTAGGGAAATGAAATGAATGGTGTTTGTAGAATTGGAGAGAATGACGTG  59193

Query  3389   TCGTGAGGTTTTGAGGCTGGTGAGATTATGTGGTCATTTTTAAAACTATTACACTAGCCG  3448
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  59194  TCGTGAGGTTTTGAGGCTGGTGAGATTATGTGGTCATTTTTAAAACTATTACACTAGCCG  59253

Query  3449   CCAAGTCATTCGTCTTCCTTTTGGTGTGACGTGGAGATTTAGTCAACACTAATGTCTTTT  3508
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  59254  CCAAGTCATTCGTCTTCCTTTTGGTGTGACGTGGAGATTTAGTCAACACTAATGTCTTTT  59313

Query  3509   CAGAGACTTGGTCTCATTGCAAATTGCTTCTTCTTCTTTTCTTGGTTGCTTCCATTACAT  3568
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  59314  CAGAGACTTGGTCTCATTGCAAATTGCTTCTTCTTCTTTTCTTGGTTGCTTCCATTACAT  59373

Query  3569   TTCTTCTGCATTGTTGCAGTCTTTTATATAAACTTTTATACATTGATCTTTTGTCGAATA  3628
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  59374  TTCTTCTGCATTGTTGCAGTCTTTTATATAAACTTTTATACATTGATCTTTTGTCGAATA  59433

Query  3629   CAAAACAGAAGATAATACTCTTAATTTATAATCTAAGGAGTAAGGATACAAAACACAAGG  3688
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  59434  CAAAACAGAAGATAATACTCTTAATTTATAATCTAAGGAGTAAGGATACAAAACACAAGG  59493

Query  3689   TGTAAACTGTGGTGAACCTGTTTGGGTTCTGATCCGAACTAGTACAACAATAGTCTATAT  3748
              |||||||||||||||||||||||||||||||| ||||||||||||||||||||||||||
Sbjct  59494  TGTAAACTGTGGTGAACCTGTTTGGGTTCTGATCCCAACTAGTACAACAATAGTCTATAT  59553

Query  3749   CTTGAAATCTTTCCAAAAATGGTTTCTTAAATAAAATGGTCTTTGAATAGCCAATCTAAA  3808
              |||||||||||||||||||||||||||||||| |||||||||||||||| |||||
Sbjct  59554  CTTGAAATCTTTCCAAAAATGGTTTCTTAAATAAAAGGGTCTTTGAATAGCCAAGCTAAA  59613

Query  3809   TCCAATAGCTCTGTTAAGATATATCCATAGAGCCCCTCCTACGAATCACACTGAGACCTC  3868
              |||||| |||||||||||||||||||||||||||||||||||||||||||| ||||||
Sbjct  59614  TCCAATTGCTCTGTTAAGATATATCCATAGAGCCCCTCCTACGAATCACACTGTGACCTC  59673

Query  3869   TCCAGAGAGTTTTACTTCTTTGGTATCCGACCATAATGCCTCTGGCGTATTCTAAATGCC  3928
              ||||| |||||||||||||||| ||||||||||||||||||||||||||||||||||||
Sbjct  59674  TCCAGGGAGTTTTACTTCTTTGTTATCCGACCATAATGCCTCTGGCGTATTCTAAATGCC  59733

Query  3929   GGNTTTCGTAGCA  3941
              || ||||||||||
Sbjct  59734  GGTTTTCGTAGCA  59746
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8. Claims 2, 6-8, and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796 December 12, 1995).

The term "complement" is not defined in the instant specification; therefore the phrase may be read broadly. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *in re Morris* , 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *in re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification wherein the phrase "complement" can be read as any fragment which shares a percent identity with SEQ ID NO. 5272.

With regard to Claim 2, Brennan teaches the total array represents every possible permutation of the 10-mer oligonucleotide (Column 9, lines 53-55), therefore Brennan teaches a 10-mer which would be a complement to SEQ ID No. 5272.

With regard to Claim 6, Brennan teaches every possible 10-mer oligonucleotide therefore the nucleotides would comprise a part of a promoter, regulatory, or intron region because the claim language encompasses even up to one nucleotide of a promoter, regulatory or intron region.

With regard to Claims 7-8, Brennan teaches a 10-mer which would be a complement to SEQ ID No. 5272. Though Brennan does not teach hybridization conditions, Brennan does teach the product claimed therefore would encompass the same functions as the claimed nucleic acid and would therefore hybridize with sufficient stability. MPEP §2111-14, first section, states "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be

distinguished from the prior art in terms of structure rather than function." Therefore, for the purposes of examination, the functional limitations of hybridization set fourth in Claims 7-8 are considered not to have structural impact and will not be treated as limitations to the claims.

With regard to Claims 12 and 14, Brennan teaches a substantially purified first nucleic acid molecule (e.g. a 10 mer) which is homologous to SEQ ID No. 5272. The 10 mer would comprise 10 nucleotides that are identical to 10 nucleotides of SEQ ID No. 5272 and therefore would be at least 90% identical.

With regard to Claim 13, the 10 mer that Brennan teaches would also hybridize to any other sequence, which has the same 10 nucleotide sequence (e.g. 100% identical to non-Arabidopsis thaliana homologue).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

JEANINE A. GOLDBERG
PRIMARY EXAMINER
7/9/07